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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/783,633
Filing Date: February 14, 2001
Appellant(s): BAILEY ET AL.

J. Peter Paredes (Registration No.57,364)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 27, 2011 (and addendum filed February 14, 2011 appealing from the Office action mailed March 25, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal: (Corrections to applicants noted appeals are in bold)

Board Decision of present application 09/783,633 decided on February 21, 2008, Appeal NO. 2008-0216.

Board Decision of related application 09/707,685 decided on September 29, 2008, Appeal No. 2008-1316.

Board Decision of related application 10/258,087 decided on December **22**, 2008, Appeal No. 2008-1062.

Board Decision of related application 09/716,146 decided on April 30, 2008, Appeal No. 2007-3212.

Board Decision of related application 10/672,695 decided on March 31, 2009, Appeal No. 2008-5417.

Pending Appeal of application 09/716,146, Appeal No. 2010-7338.

Pending Appeal of application 11/327,795, **Appeal No. 2011-5576**.

Pending Appeal of application 09/707,685, **Appeal No. 2011-2092**.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 68, 69, 71-78, and 80-85

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner.

The rejection of claims 77-78 and 80-85 under 35 U.S.C. 103(a) as being unpatentable over Freitag (US 5,601,593) in view of Pollock et al. (US 2007/0255395 A1).

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,601,593	Freitag	02-1997
6,406,493 B1	Tu et al.	06-2002
5,591,197	Orth et al.	01-1997
5,562,641	Flomenblit et al.	10-1996

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 68, 69, and 71-76 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Freitag (US 5,601,593). Freitag discloses a sensor device (stent 1 considered the "sensor" as it is capable of providing a sensing function, see fig.1 or fig.2) comprising a plurality of structural elements (3, 4, 6-9; all struts of the stent), the plurality of elements including a first region (3 or 6) of a first material having a transitional temperature and coefficient to expand from a first to a second state (col.4, lines 20-22, 30-33),

the plurality of elements including a second region (4 or 7) of a second material having a higher transitional temperature and coefficient (col.4, lines 22-24, 34-39) which allow for a change in geometry of the second region in the second state upon application of a force to the sensor device, wherein the change in geometry changes the positioning of the second region (4) relative the first region (3) during the higher transition temperature (application of heat to above 40C), the first and second materials being shape memory or superelastic (nitinol, col.4, lines 20-25). Freitag discloses sensor device's (stents considered a "sensor" as it senses temperature) are typically implanted endoscopically (col.1, lines 15-20; endoscopes have optical abilities to view proper positioning of the stents in the vessel thus the endoscope specifically its view screen may be considered the detection mechanism as it is the means in which the surgeon detect the change by viewing this on the screen). If not inherent that an endoscope's viewing element (detection mechanism) is present, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the stent with an endoscope with viewing element to ensure the stent is positioned at the correct location in the vessel needing treatment and ensuring proper expansion has taken place. The superelastic and shape memory materials used by Freitag are responsive to temperature, flow rate and plaque build up as the material may move elastically by the pumping of blood and force by tissue buildup or tissue attachment to the stent surface.

Claims 68-69 and 71-76 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tu et al (US 6,406,493 B1). Tu discloses a sensor device (annuloplasty stent considered the "sensor" as it is capable of sensing temperature, see fig.1; col.4 line 66-col.5 line 2) comprising a plurality of structural elements (11, 13a-b, 14a-b), the plurality of elements including a first region (13a) of a first material having a transitional

temperature and coefficient to expand from a first to a second state (col.6, lines 42-53), the plurality of elements including a second region (14a) of a second material having a higher transitional temperature and coefficient (col.6, lines 54-65) which allow for a change in geometry of the second region in the second state upon application of a force (temperature forces open) to the sensor device, wherein the change in geometry changes the positioning of the second region (14) relative the first region (13) during the higher transition temperature (col.6, lines 54-65), the first and second materials being shape memory or superelastic (col.6, lines 9-29). Tu discloses the sensor device (annuloplasty stent) to be used with RF energy, IR energy, ultrasound, laser, catheter, fiber optics, etc, which typically include imaging means that may be considered the detection mechanism (as the image displayed shows the change to the surgeon) as the application of heat/energy need be correctly positioned within the stent in order to assume proper positioning and expansion. If not inherent that the disclosed heat applicators (ultrasound, fiber optics, RF, IR) contain imaging capabilities (detection mechanism), it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the annuloplasty stent with an imaging means (detection mechanism) to ensure the annuloplasty stent is positioned at the correct location in the vessel needing treatment and ensuring proper expansion has taken place. The superelastic and shape memory materials used by Tu are responsive to temperature, flow rate and plaque build up as the material may move elastically by the pumping of blood and force by tissue buildup or tissue attachment to the stent surface.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 77-78 and 80-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orth et al. (US 5,591,197) in view of Flomenblit et al. (US 5,562,641). Orth discloses a sensor device (stent, see fig.5) comprising a plurality of structural elements (13, 16, 20; 11, 12, 20), the plurality of elements including a first region (13 or 12) of a first material that expands from a diameter to a second diameter, the plurality of elements including a second region (20) of a second material which allow for a change in geometry of the second region, wherein the change in geometry changes the positioning of the second region (20) relative the first region (13 or 12), the first and second materials being shape memory or superelastic (col.9, lines 30-32). Orth discloses using typical intraluminal delivery systems using guidewires with typically include imaging means that may be considered the detection mechanism as the imaging need be present to correctly position the stent in the treatment location of the vessel. If not inherent that the disclosed delivery devices contain imaging capabilities (detection mechanism), it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the stent with an imaging means to ensure the stent is properly positioned and expanded. Orth discloses the stent to be made of superelastic or shape memory materials (col.9, lines 29-31), the first and second regions (13 and 20) possibly being made of different materials (col.10, lines 39-42), and expanding at different times (fig.5, 6 and corresponding description; col.9, lines 1-15) however using a mechanical means to expand instead of temperature and also expands 20 before 13 instead of vise versa. Flomenblit teaches in the same field of stents, the use of different transitional temperatures/coefficients at different regions of the stent for better control over the

positioning of the stent in the vessel (can control portion by portion; col.6, lines 13-67; see figures). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Orth's piecewise stent (having first and second regions 13 and 20 that expand at different times independently) with Flomenblit's teaching of using two different transitional temperatures to expand different portions of a stent at different times, in order to provide a Orth's stent with increased control over individual regions during implantation such that first region (13) has the first transitional temperature and the second region (20) has the second transitional temperature. With these materials, Orth's stent would function in the claimed manner-second elements (20) would have a first coplanar position after the first elements (13) radially expand and a second projecting position after elements 20 expand.

The superelastic and shape memory materials used by Orth are responsive to temperature, flow rate and plaque build up as the material may move elastically by the pumping of blood and force by tissue buildup or tissue attachment to the stent surface.

(10) Response to Argument

I. The applicant has argued that Frietag (US 5,601,593):

(a) does not disclose EACH structural member to have a first region made of a first material and second region of a second material (that is a single wire element composed of two regions/materials). The examiner disagrees. The claims do not require EACH structural member to be made of two materials. The claims instead require the collection of structural members (the plurality of structural members) to comprise two different regions/materials. No claim limitations are present as to where exactly these two regions of different materials are located. Freitag shows clearly a plurality of structural elements (all struts making up rings 3 and

rings 4 in fig.1 for example), some structural members (first top ring 3 for example) is considered the first region and is made of a first material and other structural members (next ring 4) to be considered the second region and made of a second material which meets the claims. The location of the first structural members (3) is considered a first region and the location of the second structural members (4) is considered a second region.

(b) does not disclose a change in geometry of a second region relative a first region during the second temperature on a single structural element. Applicant argues the change in geometry must be on the structural element itself, not a separate structural element. The examiner disagrees. Referring back to section (a) above, under the examiners interpretation, struts of ring (3) is a first region and struts of ring (4) is a second region. Freitag clearly disclose the two regions (3 and 4) to be different materials and have different transitional temperatures, the second region (4) transitioning after the first region (3) has already transitioned into a second diametric state (col.4, lines 20-40). As the structural elements of ring 4 expand, they change shape and move with respect to the structural elements of first region (3). This occurs after being in the second diametric state (after expansion of 3) and at the second transitional temperature (40 degrees C).

(c) does not disclose an ex vivo detection mechanism. The examiner disagrees. First, "ex-vivo" is not claimed, thus not required. It seems applicant is reading limitation from the specification into the claims. The claims only require a "detection mechanism". No location of the detection mechanism, nor type of detection mechanism has been claimed. Even if ex-vivo was required by the claims, although an endoscope is placed in the body, the image from the endoscope displaced to the surgeon is external of the body (ex-vivo). As endoscopes show images, an image of the

first configuration and an image of the second configuration will be displayed to the surgeon. The difference between the two images is the change in geometry. Endoscope may be defined as: a slender, tubular, optical instrument used as a viewing system for examining a part inside the body-emphasis added. By its definition endoscope contains a means for detecting (the view or image of the endoscope or even the surgeons eye). Applicants further argue that an endoscope would not be capable of detecting such a small change, as stents are small objects in the order of millimeters. The examiner disagrees. The purpose of endoscopes is specifically for viewing small objects in the body. Further, the applicant has provided no evidence that an endoscope could not be capable of detecting the change in geometry of Freitag's stent.

II. The applicant has argued that Freitag is not obvious as:

(a) Freitag does not render obvious an ex-vivo detection mechanism that detects physiological events such as temperature, blood pressure, shear stress, endothelialization and arteriosclerosis. The examiner disagrees. First, "ex-vivo" is not claimed. Second, even if ex-vivo was claimed, an endoscope may be considered an in vivo or ex vivo detection device, since it may be inserted in vivo, however the image displayed to the surgeon is ex vivo. These types of imaging devices are well known in the art to produce an image for the surgeon to see, such that they can verify the implant is positioned properly and has expanded properly (in this case two separate expansions). Third, the claims do not require detection of physiological events. Fourth, Freitag's stent is designed to be responsive to changes in pressure or temperature. Whether these temperature and pressure changes occur naturally in the body or are applied externally is irrelevant. If Freitag's stent has specific transitional temperatures which cause the stent to change shape at those

specific temperature when reaching these temperature, the shape change with occur when this temperature is met naturally or artificially applied.

(b) applicant argues Freitag's stent is not a sensor and it does not detect physiological changes in the body. The examiner disagrees. Freitag's stent is as much a sensor as applicants stent is a sensor. Both are made of shape memory/superelastic materials that respond to different temperatures/forces (temperature and force both which may be considered a physiological condition). The intended function/purpose is argued by the applicant to be different, however this is irrelevant has Freitag's possesses the structure and materials claimed which is capable of applicants intended use. Also, "physiological events" are not claimed.

III. The applicant has argued that Tu (US 6,406,493 B1):

(a) does not disclose EACH structural member to have a first region made of a first material and second region of a second material (that is a single wire element composed of two regions/materials). The examiner disagrees. The claims do not require EACH structural member to be made of two materials. The claims instead require the collection of structural members (the plurality of structural members) to comprise two different regions/materials. No claim limitations are present as to where exactly these two regions of different materials are located. Tu shows clearly a plurality of structural elements (all struts making up implant seen in fig.2a for example, including structural elements 13a, 13b, 14a, 14b, 11a, 11b, etc), some structural members (13a) is considered the first region and is made of a first material and other structural members (14a) to be considered the second region and made of a second material which meets the claims (col.6, lines 16-23). The location of the first structural members (13a) is

considered a first region and the location of the second structural members (14a) is considered a second region.

(b) does not disclose a change in geometry of a second region relative a first region during the second temperature on a single structural element. Applicant argues the change in geometry must be on the structural element itself, not a separate structural element. The examiner disagrees. Referring back to section (a) above, under the examiners interpretation, 13a is a first region and 14a is a second region. Tu clearly disclose the two regions (13a and 14a) to be different materials and have different transitional temperatures, the second region (14a) transitioning after the first region (13a) has already transitioned into a second diametric state (fig.2b shows the implant at the first transitional temperature; fig.2c shows the implant at the second transitional temperature; col.6, lines 42-65). A change in geometry is disclosed and shown at each temperature.

(c) does not disclose an ex vivo detection mechanism. The examiner disagrees. First, "ex-vivo" is not claimed, thus not required. It seems applicant is reading limitation from the specification into the claims. The claims only require a "detection mechanism". No location of the detection mechanism, nor type of detection mechanism has been claimed. Tu makes use RF energy, IR energy, ultrasound, laser, catheter, fiber optics, etc, which are considered inherently to have a display on them for the surgeon to see inside the body. An image of the first configuration and an image of the second configuration will be displayed to the surgeon. The difference between the two images is the change in geometry. The applicant argues that the purpose of the devices (RF, IR, ultrasound, fiber optics, etc) is to apply heat, not for detecting. Although it is true the primary purposes of these devices is to apply heat to effect a conformation change in the stent,

the devices also have the capability of functioning as a detection mechanism as they display images or video to the surgeon so the surgeon sees the change. The applicant further argues Tu's stent cannot be considered a sensor as it does not react to physiological events in the body. The examiners disagrees. First, physiological events are not claimed. Second, the heat applied to the body by RF, ultrasound, fiber optics, etc, is causing a change in the physiological conditions in the body, and as the stent is reacting to this change by a change in conformation, the stent is functioning as a sensor. The applicant seems to be arguing language that is not present in the claims. All the claims require is the presence of a detection mechanism. The RF energy, IR energy, ultrasound, laser, catheter, fiber optics, etc are considered the detection mechanism since they display images to the surgeon of the shape changes that occur, noting also that some of the same detection mechanisms listed by applicant are the ones used by Tu. Both disclose use of ultrasound. Thus is applicants uses ultrasound as a detection mechanism, then Tu's ultrasounds may be considered a detection mechanism as well as they are using the same device as applicant it may be considered capable of functioning in the same manner that applicants use theirs.
IV. applicant repeats their same argument here with respect to Tu above. The examiners position is that if not inherent that any of RF energy, IR engery, ultrasound, fiber optics have an image display, one would have been obvious such that the performing surgeon may view the application of heat and make ensure successful positioning as well as shape change/expansion. This is well known in the art

V. The applicant has argued that Orth et al. (US 5,591,197) in view of Flomenblit (US 5,562,641):

(a) is not an obvious combination, the two references combined do not disclose the limitation of conformation change from the first to the second position while in the second diametric state. The examiner disagrees. Orth discloses a piece meal stent with separate sections 11, 12, and 20/22, see figures 5 and 6. Orth expands sections 11 and 12 separate from section 20 as the two have different functions. Sections 11 and 12 expand to a larger diameter to be flush with the vessel wall. Section 20 moves to protrude further outward to pinch the vessel wall. The different sections are independent and may be deployed simultaneously OR at different times (col.9, lines 1-12). Orth's device is deployed mechanically rather than by temperature transition. The purpose of the Flomenblit teaching is to show using different transition temperature regions is an alternate method to cause changes in shape of different sections at different times (one after the other) on a piece wise stent. Flomenblit teaches different sections may be transitioned first, middle or last and this may be tailored to the specific condition being treated. This concept applied to the piecewise stent of Orth (providing stent sections 11 and 12 with the first material and stent sections 20 with the second material of different transitional temp) produces a stent that will change shape at two different times (it is obvious to use this teaching to have sections 11 and 12 of a first transitional temperature and section 20 of a second transitional temperature-which would function in the claimed manner).

(b) the applicant argues that Orth's two transitions occur together during expansion at the same time (not after one after expansion-the second diametric state). The examiner disagrees. Orth discloses a piece wise stent with different regions 11, 12, and 20. Regions 11 and 12 expand from a first to a second diameter and region 20 projects radially outward in the form of barbs to engage tissue. Although the two may occur simultaneously as applicant has noted, they also may

occur separately at different times (col.9, lines 6-13). The different regions have different independent functions and are actuated separately at different times. Orth discloses actuating the barbs 20 first, instead of second as claimed however. Flomenblit is used as a teaching of using transition temperatures so that one can tailor different portions of the stent to change conformation or expand at different times. Applying this concept of tailoring different sections with different transitional temperatures to Orth, it would have been obvious to have Orth's sections 11 and 12 of the first transition temperature and second section 20 of the second transitional temperature. With the sections having different transitional temperature, they would function in the claimed manner (second region 20 changing geometry when exposed to the second transitional temperature, this occurring after stent expansion-after the first transition). The applicant has also argued that sections 11 and 12 of Orth may not be considered the first region and section 20 may not be considered the second region as they are separate structures. The examiner disagrees as it is again noted that the claims do not require EACH wire to have two different regions/materials-instead the claims require the plurality of structural elements (grouping of all struts) to comprise a first and second region. Second region (struts 20) are shown coplanar with respect to first region (11, 12) in figure 5 and 5a; and second region (struts 20) are shown projecting away from first region (11, 12) in figure 6a.

(c) applicant argues that Orth's second region (20) does not project from the surface of the first region (12, 11). The examiner disagrees. See figure 6a. Second region (20) clearly is shown attached to first region (11 or 12) at lines pointing to 20a and 20b in fig.6a and is shown projecting away from its surface. The applicant also argued that Orth does not disclose a detection mechanism. The applicant argues that if the stent is attached to the aortic wall would

not be detectable by a detection mechanism. The examiner disagrees. The change in stent length alone (shrinking as the hooks 20 angle outward) would be considered a detection of the change of configuration. Orth discloses use of guidewires with the stents, the guidewires considered inherent to have imaging capabilities which would detect the change in shape (the detection mechanism could even be considered the surgeon him/herself as they see the change in shape). If not inherent that the guidewire or catheter system of Orth is used with an image display, it would have been obvious as these are well known features on guidewires and catheter systems so that the surgeon may watch the positioning and deployment of the implants to make sure they were successfully placed and actuated.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are have been provided with applicants appeal brief.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Cheryl Miller

/Cheryl Miller/

Examiner, Art Unit 3738

Conferees:

/CORRINE M MCDERMOTT/

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